

AMENDMENTS TO THE DRAWINGS

A marked-up sheet and a replacement sheet are submitted herewith amending Fig. 7.

REMARKS

Claims 1-7, 9-13, and 15-30 appear in this application for the Examiner's review and consideration. Of these, new claim 5 has been amended. The reinstatement of claims 18-28 for consideration is sincerely appreciated.

The drawings were objected to for not showing an injection device. Fig. 7 has thus been amended to schematically show such a device, and the specification has been amended accordingly. The amendments are fully supported in the originally filed specification, claims, and drawings, as explained below.

Claim 5 was objected to as being a copy of claim 3. Although claim 5 dealt with an injecting end of the needle, instead of the piercing end recited in claim 3, claim 5 has now been amended to provide proper antecedent basis for the recited "injecting tip".

Claims 1-7, 9-13, 15-17, and 22-30 were rejected under U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action argued that no reference is made in the abstract as to the term "jet injector". In particular, the Office action cited the abstract that was submitted on November 22, 2002, as being the "originally filed abstract". It is respectfully noted that the November 2002 abstract was not the original abstract, but was instead filed with the Amendment of the same date to replace the language of the actual originally-filed abstract, since the originally filed abstract was objected to for its format. The originally filed abstract was filed as part of the originally filed application on October 20, 2000, and a copy is submitted herewith for the Examiner's convenience.

It is clear that the original abstract discloses a jet injector in its first sentence. Consequently, the present and prior amendments reciting and showing the jet injector or jet injection device are fully supported by the original disclosure in the present application. As explained in the remarks of the August 31, 2004 Amendment, the abstract is part of the specification (37 C.F.R. § 1.77(b)), and the M.P.E.P. is clear that the abstract is considered to be "a part of the specification for purposes of compliance with paragraph 1 of 35 U.S.C. 112 . . ." (M.P.E.P. 608.01(b) (citations omitted)). Withdrawal of this rejection is respectfully requested.

Claims 1-6, 9-13, 16, 18-20, 23-27, and 30 were rejected under 35 U.S.C. § 102(b) over Malay. Also, claims 7, 17, 21, 22, and 29 were rejected under 35 U.S.C.

§ 103(a) over Malay in view of Sudo; claim 15 was rejected over Malay in view of Kwee, and claim 28 was rejected over Malay and Sudo.

All of the claims are directed to a jet injector or jet injection, which claim term should be given weight in the examination as explained above and in prior amendments. As explained previously, it is well known in the art that jet injectors inject medicaments by creating a high speed jet of the medicament that penetrates the tissue of the patient as a jet to a significant distance beyond the end of the injector. Some jet injectors are called needle-assisted jet-injectors because they use a needle to penetrate the patient tissue by a short distance, and the energy created in the jet is used to fire the medicament significantly deeper into the tissue. It is also known that jet injectors require certain components to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These components include, for instance, an energy source to drive the plunger when the injector is fired, a trigger to allow a user to fire the injector, and carefully dimensioned and configured jet nozzle to efficiently form the high speed jet. Due to the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand. New claim 23 further clarifies that the jet injector is configured for jet injection of the medicament from the fluid pathway.

On the other hand, not only is Malay not related to jet injectors, it is not related to injectors in the first place. The Malay teaching is for extracting fluid from a patient (*see, e.g.*, Malay 6:12), such as a blood specimen. Additionally, as shown with reference to the Malay figures, there is no space between the slideable member 34 and gasket 32 at the beginning of operation that could even contain the claimed medicament to be injected. It is only after the Malay needle is made to protrude from the outer tube 2, as shown in Fig. 7, that the plunger is withdrawn (Malay 6:12-14.).

Also, the configuration of Malay does not have any state in which a medicament can be retained in a tube between two or more stoppers, wherein the stoppers can be moved so that the needle pierces the first stopper to expel medicament. Fig. 9 of Malay, for instance, shows the inner tube 28 being removed from the outer tube once it is filled with the fluids that have been extracted from the patient. (Malay 6:33-35.) Thus, there is no teaching or suggestion of modifying Malay to be any type of injector, much less a jet injector, and it is not possible to position the Malay device to provide the injector of any of the claims in which the medicament is contained between two movable stoppers prior to injection. Consequently, at least claims 1, 17, 18, or 30. At least claims

20, 22, and 23 define further features of jet injection and are also not taught or suggested by the references.

Claims 1 and 30 recite that the first and second stoppers are within, against, and moveable within a lumen. Such a structure is not found or suggested in Malay. While slideable member 34 is slideable within the inner tube 28, the gasket 32 is not. All of the figures show that the gasket 32 remains in place throughout the operation of the Malay device. The figures also show that the slideable member 34 is not disposed against the outer tube 2. Claims 1 and 30 are thus patentably distinct over the references for this reason as well.

The subject matter of claims 18 and 24 is also patentably distinct from the references of record, since the references neither teach nor suggest providing the first stopper to substantially prevent any of the medicament contained in the cartridge from contacting the needle prior to the firing of the jet injector. There is no medicament in Malay in the first place, and claims 18 and 24 provide the surprising benefit that the sterility of any medicament within the cartridge can be maintained until the injector is fired. Additionally, as disclosed in the specification of the present application, certain medicaments, such as those containing insoluble particles, tend to clog the needle if in contact therewith prior to injection, and claims 18 and 24 thus provide the additional surprising benefit that these types of medicaments can be more reliably employed.

Claims 18 and 24 are thus patentably distinct from the references on its own merits.

Claim 26 further defines that the medicament cartridge comprises only the two stoppers that contain the medicament there between, and claim 27 additionally recites that the medicament cartridge is configured such that all of the medicament in the cartridge is injected together. Claim 28 recites that the first stopper is free of any device to puncture another of the stoppers. There is no motivation or suggestion to modify Malay to contain any medicament, since it is not intended for this purpose, and each of these claims are patentably distinct from the references of record on their own merits.

Sudo teaches a device for dosing the human body with a medicament. There is no motivation to modify the Malay teaching with the teaching of Sudo, since Malay is meant to extract fluids from the body, not dose them into the body. Additionally, based on the configuration of Malay, there is no place to even put a medicament that would later be injected, so it is not readily modifiable to function to inject a liquid. Furthermore, a modification of Malay to contain a liquid to be injected before the needle has punctured the gasket 32 would defeat the intended purpose of the

Malay teaching, and for this reason as well, so these two references are not properly combinable as in the rejection. Finally, the Sudo teaching does not remedy the deficiencies of the Malay teaching in terms of providing all of the elements of the claims.

With respect to the rejection of claim 15, Kwee also does not remedy the deficiencies of Malay, and is not properly combinable therewith for the reasons discussed with respect to Sudo, since Kwee is also directed to the injection of drugs, instead of the extraction of fluids. Also, Kwee does not teach or suggest a jet injector.

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,

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Marked-up Sheet

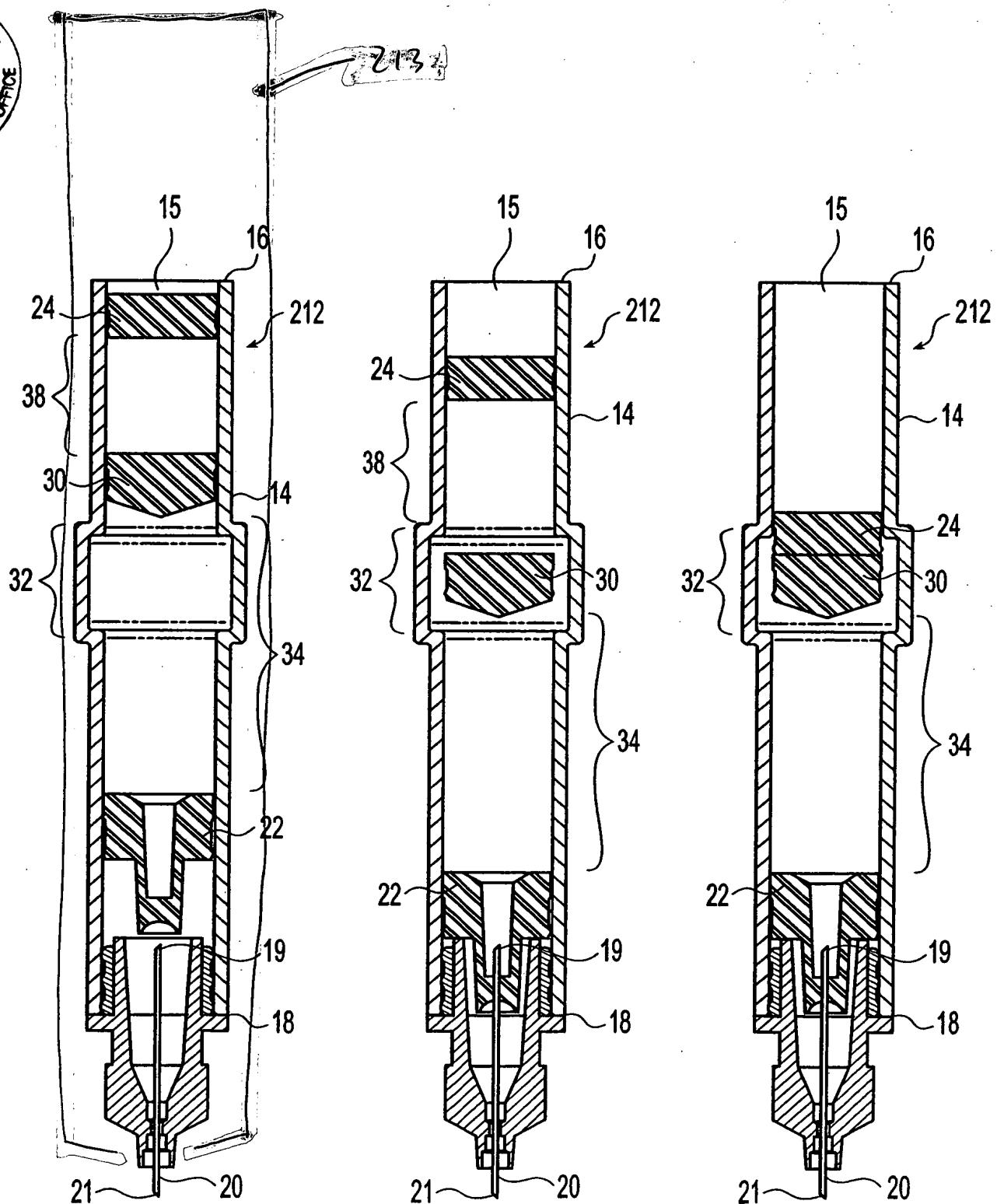


Fig. 7

Fig. 8

Fig. 9